SPS Measures
LEARNING MODULE THREE
An Introduction to Risk Assessment
Final Draft: 4/7/99

Introduction for the User

This module is intended primarily for program managers at the policy level in Ministries of Agriculture outside of the United States. It also serves as an introduction to risk assessment for their technical staff, who may then wish to receive further training in the subject. U.S. commodity groups who have concerns about or need help with imports or with exports are also potential audiences for this module.

The other audience is internal to USDA and consists of people who will either present the module or help others with access to it either through the CD-ROM or the Web-based versions. Overseas they are primarily the Agricultural Attachés, either from APHIS or FAS. In the US they are the staff of IS and others who make presentations to visitors (some of whom are APHIS trading partners who come to the US). An alternative to a presentation is to help them with access to the CD-ROM or Web-based versions. The presentation should last up to an hour. The estimated time for viewing the CD-ROM or Web-based versions is up to an hour.

At various points in these materials there are endnotes with definitions of key terms. They can serve as a reference and for review purposes at the end of the module.

Goal and Learning Objectives

The goal of Module 3 is to explain the APHIS interpretation of what risk assessment is, why it is important, what risk assessment does and what it does not do, what it takes to get a good assessment done and what the international guidelines are. Some of the key elements of this understanding are that it will take work to obtain the information needed to get a good assessment done in order to move toward approval of a plant or animal commodity for importation into the US by a given country. Another important concept is that a risk assessment is an organized, systematic presentation that may include a recommendation but that it does not determine the policy. That decision is up to policy makers who take into account the findings of the risk assessment. Though the focus of this module is risk assessment, it begins with a brief overview of the risk analysis process as defined by APHIS in order to place risk assessment in the proper context.

Getting Started

You may wish to use some or all of the following text as a welcoming statement and as a way to help visitors participate in their learning process.

Welcome to the USDA Introduction to Risk Assessment. We are confident that

you will find this session useful. We will try our best to explain what risk assessment is and what it does. Because risk assessment is a complex topic, we are limiting this introduction to an overview.

Before starting the session we would like to encourage you to write down what you hope to learn and to note the two or three most important questions you would like answered. Please keep track of these items as you go through the module to identify where the answers appear. You may need to refer to some of the reference material that is also provided for more detailed answers.

Explain that you want to make sure you have an idea of what their needs and interests are, and that there is value in having them hear what other visitors hope to learn and what their questions are as well.

Let's hear what each person hopes to learn today. I do not plan to address all of your questions at this point, but I do intend to refer to many of them throughout the session.

Ask each visitor to read out loud to the group what they hope to learn.

Please read aloud what you hope to learn. Let's have one item per person to start with so we can hear from everyone.

Write their answers on the board or flipchart as they read them, and clarify/paraphrase as appropriate to make sure you have understood the meaning of their answer. Do not try to address what they offer at this point. Place a checkmark next to those that are repeats.

Once you have completed writing what they hope to learn and what their questions are, read them over and identify which ones will be addressed in this module and which ones may be addressed in another module. Avoid getting into a discussion at this point unless it is to clarify a question. Then proceed with the module as described below.

Here are the questions we will cover in this module. Now that we have identified your most important questions, let's begin with a discussion of the objectives of the module so that you may see where some of your questions will be addressed and so you can track your progress in the session.

Show each slide and read the wording with a brief explanation, if necessary.

Slide 1. Learning objectives

Slide 2. The APHIS Risk Analysis Process

The results of APHIS risk analyses provide well-supported recommendations to APHIS decision-makers to ensure safe trade. The risk analysis process is transparent to APHIS trading partners through the full sharing of information during the risk analysis process, in accordance with the SPS Agreement.

Here are more detailed definitions of the three processes of risk analysis: Risk assessment, risk management and risk communication, with more attention devoted to risk assessment, the main topic of this module.

Slide 3. Risk Assessment

See endnote 1: SPS Agreement definition of risk assessment.

Slide 4. What risk assessment evaluates

In many cases, broad agreement concerning this risk negates the need for formal risk assessments.

Formal risk assessments are conducted when the unmitigated risk is not clearly acceptable or unacceptable. These assessments are also important when assumptions concerning the level of unmitigated risk are challenged or when new information concerning the unmitigated risk has been provided. The assessment of risk at this level typically involves the evaluation of origin, commodity, and destination factors.

Slide 5: Origin Risk Factors

Slide 6: Commodity Risk Factors

Slide 7: Destination Risk Factors

This process is also known as hazard identification.

Slide 8. Hazard identification

See endnote 2: Hazard identification

Once a risk assessment has been completed, the next step is risk management.

Slide 9. Risk management

There are some situations where an appropriate standard does not exist.

Slide 10. Determining levels of protection

One of the key aspects of the SPS Agreement is transparency.

Slide 11. Transparent processes

See endnote 3: Transparency

Risk communication is how APHIS maintains transparent processes.

Slide 12. Risk communication

This includes the active exchange of information throughout the risk analysis

process with involved parties and the communication of the conclusions of risk analyses to all interested and affected parties. This process includes routine interaction with the scientific community to ensure the validity of scientific data, methods, and assumptions.

Slide 13. Communication about regulations

Slide 14. Overview of the risk analysis process

The purpose and possible outcomes of a risk assessment

Purpose

Risk assessment is one of the key concepts and methods used to determine whether an animal or plant commodity can be approved for importation into the United States as well as to other countries. It is intended to contribute to transparency in decision-making in conformance with the SPS Agreement.

The SPS Agreement *(covered in Modules One and Two) stipulates that in assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary and phytosanitary*

protection from such risk, WTO members shall take into account as relevant economic factors. They will also avoid trade-restrictive measures.

Slide 15. Relevant economic factors

Slide 16. Avoiding trade-restrictive measures

It may be useful to look at what risk assessments do and what they do not do.

Slide 17. What risk assessments do

See endnote 4: definition of probability

Slide 18. Risk assessments do not

See endnote 5: definition of acceptable risk.

Risk assessment may consider assessing the reliability of data by evaluating the quality of the surveillance system in a given country, including such things as the laboratory capabilities and other aspects of the exporting country's quarantine programs.

Slide 19. What risk assessments should describe

See endnote 6: definition of uncertainty

Getting Started

The APHIS approach is to start by defining the risky or hazardous activity – Hazard Identification. It is important to be precise and clear about what you want to evaluate through a statement of undesired outcome. Here are some examples of precise and imprecise statements.

Slide 20. Example of a precise activity statement.

Slide 21. Precise statement of undesired outcome

A precise statement describes a commodity with numerical and geographic detail and other information such as current requirements for entry or other data that enable the risk assessor to limit the number of variables that need to be analyzed.

An imprecise statement describes a risk that contains a large number of potential variables. The result is that there is such a high degree of uncertainty that it is nearly impossible to analyze the risk and thereby determine the likelihood and magnitude of adverse effects.

Slide 22. Imprecise statements: risk assessment impossible

The types of questions risk assessors ask could be boiled down to the following

Slide 23. Risk assessment questions

Risk assessment approaches

Risk assessors may proceed by using approaches defined as qualitative and/or quantitative. Often risk assessments include a combination of both. A key principle in whatever approach is transparency, sharing the information with all interested parties.

Slide 24: The qualitative approach

Slide 25: The quantitative approach

Explain that the examples relating to animal and animal products are subject to the regionalization regulation covered in Module 2. A reminder here that APHIS responds to requests from foreign countries to recognize areas as free from a particular foreign animal disease or diseases or some other defined category of risk for importation of that disease. APHIS does not perform a risk assessment for importation of a single shipment of animals or a commodity.

For a brief explanation see endnote 7: Regionalization

Slide 26: Example of a Qualitative Assessment – Scope of the analysis

Slide 27: Example of Qualitative Assessment – information submitted

Slide 28: Example of Quantitative Assessment - Scope

Slide 29: Example of Quantitative Assessment – Data Analysis

Typical of many situations a qualitative assessment was also conducted for the classical swine fever example cited above. It considered all of the factors listed under the qualitative risk assessment example.

Slide 30: Summary – what we can expect from a Risk Assessment

Guidelines for Risk Analysis

The guidelines for risk analysis for Plant Protection and Quarantine and for Veterinary Services contain some differences due to the type of commodities that are involved. Therefore they are treated separately in this next section.

General guidelines for risk analysis relative to Plant Protection and Quarantine

The WTO/SPS Agreement encourages WTO Members to base their sanitary measures on international standards, guidelines and recommendations. Members may choose to adopt a higher level of protection than that provided by international texts if there is a scientific justification or if the level of protection provided by the relevant international texts is considered to be inappropriate. The SPS Agreement encourages Governments to make a wider use of risk assessment.

Slide 31: SPS Measures based on an assessment

Slide 32: Initiating the PRA Process

See endnote 8: Definition of a quarantine pest.

Prior to proceeding with a new PRA, a check should be made as to whether the pathway or pest has already been previously evaluated or assessed. If a PRA exists, its validity should be checked as circumstances may have changed.

At the end of Stage 1, pests have been identified as potential quarantine pests, individually or in association with a pathway.

At the next stage assessors consider pests individually. They examine, for each, whether the criteria for quarantine pest status are satisfied:

Slide 33: Pest Risk Assessment

In doing so, the PRA considers all aspects of each pest and in particular actual information about its geographical distribution, biology and economic importance.

For potential economic importance to be expressed, a pest must become established and spread. Thus the risk of a pest, having entered, becoming established and spreading in the PRA area must be characterized.

Slide 34: Deciding whether to proceed

Slide 35: Pest Risk Management

At the end of Stage 3, the appropriate phytosanitary measures concerning the pest or pathway have been decided. Completion of Stage 3 is essential; it is in particular not justified to complete only Stages 1 and 2 and then take phytosanitary measures without proper assessment of risk management options. After implementation of the phytosanitary measures, their effectiveness should be monitored and the risk management options should be reviewed, if necessary.

Slide 36: Minimizing negative trade effects

Finally, a PRA should be sufficiently documented so that when a review or a dispute arises, the PRA will clearly state the sources of information and the rationales used in reaching a management decision regarding phytosanitary measures taken or to be taken.

General Guidelines for Risk Analysis relative to Veterinary Services

Here is an Overview of APHIS Policy Regarding Importation of Animals and AnimalProducts: As of October 28, 1997, the Animal and Plant Health Inspection Service(APHIS) of the U.S. Department of Agriculture is adopting a policyincorporating the concepts of regionalization and risk assessment asrequired by the World Trade Organization (WTO) &Agreement on Sanitaryand Phytosanitary (SPS) Measures.

A statement of this policy is published in the Federal Register, Vol. 62, No. 208.

Slide 37: APHIS Regionalization Policy

With minor exceptions, the portion of the Code of Federal Regulations (CFR) dealing with animal and animal product imports has previously been based on assigning a single disease status to the entire region defined by a country's national political boundaries.

Slide 38: Definition of a Region

Countries have typically been classified in the CFR as disease-free or affected. There has been some recognition previously in the CFR of the range of risks that countries may present through a modified-free classification in cases where a disease agent may exist in close proximity to an otherwise free country or where the import practices of the country in question suggest a slightly higher level of risk. In general, therefore, the CFR has operated under a three category risk-classification system where countries are classified as free, modified-free, or affected.

Slide 39: Benchmark risk levels

The free-with-vaccination benchmark has recently been applied to helpimplement the 20,000 metric ton tariff-rate quota negotiated for U.S.beef imports from Argentina as part of the Uruguay Round of the GeneralAgreement on Tariffs and Trade. These imports could not have beenaccomplished under the three-category system previously employed.

Slide 40: Compliance with WTO-SPS requirements

In the interests of transparency regarding the approach to evaluating the risk presented by different regions, the APHIS policy statement outlines the risk factors that APHIS will consider when evaluating requests from potential exporting regions. The policy statement also includes some guidelines regarding how these various factors will be evaluated. The information in the policy statement is presented to provide some insight into how APHIS evaluates risk but does not imply a rigid classification scheme based on the five benchmarks.

Slide 41: Requests evaluated based on merits of the individual situation

Here is an example of a request received from South Africa shows how APHIS has applied the regionalization policy.

Slide 42: Example – Background of South Africa situation

Slide 40: Request from South Africa

Slide 41: APHIS response to South Africa

We have now arrived at the end of this module on risk assessment. It may be useful to review some of the key concepts. This is also an opportunity to review some of the questions you wrote down initially to see if they have been answered or if you need to discuss them further.

Once the review of key concepts and of the questions is over thank participants for their interest and refer them to ways they can get additional information on regulations and on Risk Analysis through the USDA Web Site.

The concepts below should be copied onto a handout so that participants may review to them at this point and refer to them after the session is over.

Definition of Concepts Related to Risk Assessment

(Currently in endnote format. Could be slides for the instructor-based version and in a hyperlink reference section for the web-based version)

SPS Agreement definition of risk assessment : "the evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member (of the WTO) according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins, or disease-causing organisms in food, feedstuffs and beverages. "(SPS Annex A)

Hazard Identification : The process of identifying the biological agents that could potentially be introduced in the commodity considered for importation. A hazard: represents elements or events which represent potential harm; an adverse event or adverse outcome. In risk assessment, hazard is specified by describing what might go wrong and how this might happen. A particular item or event may not pose a hazard in itself, but its introduction into a scenario where it can cause harm presents a hazard.

Transparency: The prompt sharing with all interested parties of comprehensive documentation showing all data, assumptions, methods, results, discussion and conclusions used in a risk analysis. Conclusions are supported by an objective and logical discussion and the document is fully referenced.

Uncertainty: The lack of accurate or precise knowledge of the input values which is due to measurement error or to the lack of knowledge of the steps required, and the pathways from hazard to risk, when building the model of the scenario being addressed. It includes uncertainty:

Of the process (methodology)
Of the risk assessor (human error)
Of the organisms (biological unknowns)

Probability: The degree to which there is a likelihood that that adverse effects will occur from a pest or a disease. The evidence of existing or potential presence of a pest or disease and the likelihood of adverse effects is a key factor influencing the analysis of probability. It also is a factor that influences the degree of confidence regarding the evidence. Evidence is:

Data collected as part of a risk assessment investigation
The quantity or quality of the data that is collected.

The more resources you put in the more data you will get. The better your risk assessment, the more confidence you have in your output. The quality of evidence will help increase confidence.

Acceptable risk: Risk level judged to be compatible with the protection of animal, plant, and public health taking into account epidemiological, biological, social and economical factors. It is a management decision with regard to the permissibility of a hazard; a decision made (in the risk management process) about the safety of a regulatory decision or the acceptability of a hazardous event.

Regionalization: Under the SPS Agreement, signatory countries are committed to recognizing areas of regions of low animal disease incidence or risk and allowing trade to occur from those areas. They can do so by adapting their sanitary requirements to the health conditions of the zone or area from where a live animal or product originates. The APHIS policy now recognizes that, for the purpose of evaluating disease risk, a region may be defined as any geographic land area identifiable by geological, political, or surveyed boundaries. In other words, within a single country there may be many regions that have different risk characteristics that would necessitate the imposition of different import requirements.

Quarantine pest: A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled.